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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,606	03/11/2004	Masato Kurokawa	042190	3867

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EXAMINER	
GUDIBANDE, SATYANARAYAN R	
ART UNIT	**PAPER NUMBER**
1654	
MAIL DATE	**DELIVERY MODE**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/797,606	KUROKAWA ET AL.	
	Examiner	Art Unit	
	SATYANARAYANA R. GUDIBANDE	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 11-14* is/are pending in the application.

4a) Of the above claim(s) *8,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 11-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Election/Restrictions

Applicant's election of Arg-Gly-Asp and auxiliary amino acid sequence of Gly-Ala-Gly-Ala-Gly-Ser and polyalkylenepolyamine in their response to election restriction filed on 10/7/05 was acknowledged on 1/29/05 in a non-final office action.

Newly submitted claims 13 and 14 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the recitation of specific peptides by the trademark names such as "ProNectin F, ProNectin F2, ProNectin F3, ProNectin L, ProNectin L2, ProNectin L3, ProNectin Y, ProNectin Y2 and ProNectin Y3" lacks antecedent basis in the base claim. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13 and 14 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-8 and 11-14 are pending.

Claims 8, 13 and 14 have been withdrawn from further consideration as being drawn to non-elected invention.

Claims 9 and 10 have been canceled.

Claims 1-7, 11 and 12 are examined on the merit.

Applicant's remarks and amendment to claims in the response filed on 2/13/08 has been acknowledged and entered.

Any objections and rejections made in the office action dated 11/14/07 and not specifically mentioned here are considered withdrawn.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

Applicant's arguments, see pages 7-13, filed 2/13/08, with respect to the rejection(s) of claim(s) 1-7 under ***35 USC § 112*** have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amendments to claims.

Claim Rejections - 35 USC § 103

Applicant's arguments, see pages 13-17, filed 2/13/08, with respect to the rejection(s) of claim(s) 1-7 under ***35 USC § 103*** have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amendments to claims and applicants remarks.

Claim Rejections - 35 USC § 112

Applicant's arguments, see page 13, filed 2/13/08, with respect to the rejection(s) of claim(s) 1-2 under ***35 USC § 112 second paragraph*** have been fully considered and are

persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amendments to claims.

New grounds of Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 recites the limitation "repeated" in line 2. There is insufficient antecedent basis for this limitation in the claim. The claims depend from independent claim 1 does not recite that the term “repeated”. Also, claims as recited does not indicate the nature of repetition in claim 1whether the repetition is alternate in nature, i.e., X-Y or randomly repeated where in contiguous repetition of X is followed by contiguous repetition of X and/or Y.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant application, applicants claim a wound dressing for accelerating epidermal regeneration which **comprises at lest one polypeptide (P)** having at least one species of (X) for e. g., RGD and at least one auxiliary amino acid (Y) for e. g., GAGAGS peptides, a polyalkylenepolyamine having a molecular weight of 2000 to 60,000 d, and a sheet (s) being polyurethane wherein the polypeptide (P) and the sheet (S) are bonded by a covalent bonding.

The MPEP clearly states that the purpose of the written description is to ensure that the inventor had possession of invention as of the filing date of the application, of the subject matter later claimed by him. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997). The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the application. These include, "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed invention is sufficient" MPEP 2163.

In the instant application, applicants claim a wound dressing comprising a polypeptide (P) that in turn comprises of at least one species of peptide (X) and at least one auxiliary amino acid sequence (Y). The polypeptide (P) as recited in the claim represents any and all peptides that comprises of the peptide (X) and peptide (Y). The specification provides a disclosure on the definition of polypeptide (P) that encompasses a polypeptide of molecular weight 1000 to 1,000,000 (page 8, line 19-20). The definition of peptide (P) in the specification (page 4, line 7 to page 10, line 22) provides a very broad definition that encompasses multitude of peptide sequences that comprises of peptide sequence (X) and (Y) in an undefined sequence of unknown length. The peptide (P) as recited in the claim 1 does not provide structural features of the peptide (partial or full) such as nature of association of peptide (X) and peptide (Y) that make up polypeptide (P). In terms of specific examples of polypeptide (P), the specification provides ProNectin F (page 24, example 1), ProNectin F2 (page 26, example 2), ProNectin F3 (page 26, example 3), ProNectin L (page 27, example 4). However, the composition of each of these ProNectins and the molecular weight disclosed for each of these proNectins indicates that the polypeptide in each case is not just limited to the composition of the peptides (X) and (Y) and contains unknown structural features that is neither well defined in the specification nor recited in the claims, for e.g., ProNectin F on page 24 has been defined as "ProNectin F (product of Sanyo Chemical Industries, Ltd.), which contains the Arg Gly Asp (RGD) sequence (SEQ ID NO: 1) and the (Gly Ala Gly Ala Gly Ser)$_9$ sequence (SEQ ID NO: 8) each in the number of about 13 and has a Mw of about 110,000 d". However, there are no specific sequences corresponding to polypeptide "P" disclosed in the in the instant specification and the sequence listing filed in the instant application. There are no sequences of "P" disclosed in the instant

application wherein one or more of the "X" peptides are conjugated to one or more of "Y" peptides in the specification and sequence listing disclosed. Applicant's disclosure of ProNectin F (page 24, example 1), ProNectin F2 (page 26, example 2), ProNectin F3 (page 26, example 3), ProNectin L (page 27, example 4) to support the instant invention do not have a sequence listing corresponding to the definition of the polypeptide "P". Even the polypeptide SEQ ID NO: 49 that represents Pronectin F3 according to Example 3 only exhibits sequence corresponding to the auxiliary sequences (Y) and part of the sequence corresponds to sequences "X" as required by the claims as recited. The SEQ ID NO: 49 is Gly Val Pro Gly Val Gly Val Pro Gly Val Gly Gly Gly Ala Gly Ala Gly Ser Gly Ala Gly Ala Gly Ser Gly Ala Gly Ala Gly Ser. Therefore the genus of the polypeptide claimed in the instant application is not at all represented in the current specification. Therefore the definition of the polypeptide "P" as recited lacks written description to satisfy the definition of the claims as recited. Therefore, current specification and the sequence listing as presented in the instant application fails to provide adequate support to the claims as recited in the instant invention.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated: "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations

other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Since the specification falls short of a clear disclosure with respect to the nature of the polypeptide P as per the afore-described analysis, the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,184,348 B1 issued to Ferrari, et al., in view of US 5,916,585 issued to Cook, et al., and further in view of Lin, 1994, Journal of Biomedical Material Research, 28, 329-342.

In the instant application, applicants claim a wound dressing for accelerating epidermal regeneration which **comprises at least one polypeptide (P)** having at least one species of (X) for e. g., RGD and at least one auxiliary amino acid (Y) for e. g., GAGAGS peptides, a polyalkylenepolyamine having a molecular weight of 2000 to 60,000 d, and a sheet (s) being at least one member selected from the group consisting of polyolefin, polyurethane, polyester, polyamide, polystyrene and silicone resin, wherein the polypeptide (P) and the sheet (S) are bonded by a covalent bonding.

Ferrari, et al., discloses the composition of the peptide copolymer of RGD and GAGAGS peptides in claims 4-6 of US 6,184,348 B1 (column 141, lines 8-29). The reference also teaches that the aforementioned copolymers can be deposited onto other substrates and materials for a cell-binding surface. Such coated materials or substrates are used for wound dressing that promotes enhanced healing (Column 28, lines 35-45). The reference of Ferrari, does not teach the use of polyalkylenepolyamine or polyarylenepolyamine matrices.

Cook, et al discloses materials and methods for the immobilization of bioactive species onto biodegradable polymers. The invention is directed to hydrophobic degradable polymeric material having at least one surface thereof rendered hydrophilic by cross-linking a hydrophilic polymer layer. The bioactive species are either reversibly immobilized or cross-linked with the

cross linking agent that cross-links the hydrophilic polymer with the hydrophobic biodegradable polymeric material (abstract). Cook, et al., discloses suitable polymeric material that forms the biodegradable hydrophobic surface as polyesters of oxalic acid and polyurethanes (bridging paragraph of columns 9 and 10 and claim 4) which is the sheet (s) of the instant application. This meets the limitations of claim1 and 9. The biodegradable hydrophilic surfactant layer comprises of polyethyleneimine and other polyalkylenepolyamines (claim 7, 25 and 30), meeting the limitations of claims 1 and 7. The reference also discloses the variety of bioactive species immobilized on the biodegradable polymeric material that includes tripeptide Arg-Gly-Asp (column 6, line 60) meeting the limitations of claim 1. Example 18 of the reference uses the polymeric material of the invention for a surgical mesh made up of PGA:PLA fiber mesh and an antimicrobial drug gentamycin reversibly cross-linked to polyethyleneimine (PEI) to treat surgical wounds to prevent infection (column 21, example 18).

The references of Ferrari and Cook do not teach covalent bonding between the peptide (P) and the polymer sheet (S).

The reference of Lin teaches the covalent bonding of RGD peptide to polyurethane polymer backbone to improve the endothelial cell adhesion and growth (abstract). The reference also discloses that immobilization of RGD containing peptides onto poly9tetrafluoroethylene), poly(ethyleneterepthlate), et., polymer surfaces and the surfaces have shown to support cell attachment and spreading (page 330, paragraph 2).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Ferrari and Cook to design a wound dressing for accelerated epidermal regeneration. Ferrari, teaches the composition of the peptides ARG and GAGAGS that can be used as a coating on

materials or substrates used for wound dressing. Cook describes the material and methods for immobilization of bioactive species onto biodegradable polymers. The motivation to combine teachings of Ferrari and Cook was available in Ferrari as the reference teaches that the peptide composition may be coated on a matrix of woven fabric or film or membrane and used as wound dressing to promote enhanced healing due to attachment of cells involved in the healing and Cook describes such a method to immobilize bioactive materials onto biodegradable polymeric matrix. The reference of Lin teaches that the peptides comprising RGD sequences can be covalently bound to the polyurethane polymer matrix. There would have been reasonable expectation of success in the present instance to combine the teachings of Ferrari, Cook and Lin to design a wound dressing composition for rapid epidermal regeneration because such a method and use of polymeric matrix has been disclosed by the references. Ferrari teaches the peptides that can be used as bioactive ingredients Cook teaches the polymeric matrix composed of polyurethane sheet with hydrophilic layer of polyethyleneimine for the adsorption or cross-linking of the bioactive peptides to form the wound dressing and Lin teaches the method of covalent attachment of RGD peptides to polyurethane polymers.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole

was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/
Examiner, Art Unit 1654

/Andrew D Kosar/
Primary Examiner, Art Unit 1654